REMARKS

The Examiner provides a number of rejections and we list them here in the order in which they are addressed:

I. Claims 22-25 And 27-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over United States Patent No. 5,789,441 To Gosselin *et al.*

II. The priority statement is objected to as incomplete and correction is requested.

I. The Claims Are Not Obvious

A. The Examiner Has Not Considered All Claim Elements

"It is axiomatic that not only must claims be given their broadest reasonable interpretation consistent with the specification, but also that **all** limitations must be considered." *In re Saether*, 181 USPQ 37, 39 (CCPA 1974) (emphasis added) (reversing the Board on 103). Rather than following this requirement of Patent Law, the Examiner discounts and refuses to consider claim elements explicitly recited in the pending claims. The Examiner argues: "While the claims recite that the solution is aerosolized or is in an endotracheal tube, a bronchoscope, or a nebulizer, for example, these phrases are given no patentable weight ..." *Office Action, pg 3.*

The Applicants submit that the Examiner is not free to ignore claim elements. The Examiner has cited four cases as a basis for ignoring certain claim elements. Applicants have reviewed the four cases cited by the Examiner and find that none of these court holdings are applicable to the pending claims. Each of these cases is reviewed below.

The Examiner first cites *Union Oil Co. of California v. Atlantic Richfield Co., 208 F.3d 989, 54 USPQ.2D 227 (2000).* Applicants submit the issues in *Union Oil* involve very different claim language. The claims at issue in *Union Oil* describe a composition that is "suitable for" a particular use (*i.e.,* conventional gasoline to be used in a standard automobile engine). The CCPA upheld the lower court interpretation that the term "suitable for" encompassed any standard automotive fuel and was not directed to specialty fuels (*i.e.,* aviation or racing fuels).

The term "suitable for," however, does not appear in the present claims. Indeed, there is no attempt to create patentable limitations through "intended use" language such as "suitable for." Applicants' claims specify elements - not how the elements are used. For example, certain claims require that the solution is in the form of an "aerosol." This is not "suitable for" language - the term "aerosol" properly limits the form of the solution. Additional claims require that the solution is in a bronchoscope, nebulizer or endotracheal tube. Bronchoscopes, nebulizers and endotracheal tubes are devices - unlike "intended use" language, these devices MUST be considered as elements of the claim.

Second, the Examiner cites *In re Rosicky, 47 CCPA 859, 125 USPQ 341 (1960).* The Examiner is apparently relying on the *Rosicky* Court's rendering of a "pharmaceutical carrier" as obvious. This decision, however, was made in the context of the **absence** of any advantages established on-the-record:

> Appellant has not established by any sort of clinical data that such a quantity would be a safe or useful dosage for the treatment of any particular malady, or useful for the alleviation of specific symptoms. *In re Rosicky at 865.*

By contrast, several advantages of the proposed compositions are taught within the Applicants' specification and appear in boldface type below:

> A preferred mode of administration comprises administration to the lung. Patients who are **sick enough to require mechanical ventilation** can receive treatment with pharmacologic agents administered via the endotracheal tube which is connected to the ventilator. Alternatively, intrapulmonary delivery of pharmacologic agents to patients not requiring mechanical ventilation can be accomplished via aerosolization. Alternatively, the agent may be administered to the lung through a bronchoscope. Of course, the therapeutic agents may be investigated for their efficacy via other routes of administration, including parenteral administration. However, when the site of infection is the lung, **targeting drug delivery thereto is likely to minimize side effects and systemic consequences**. *Applicants' Specification, pg 22, ln 12 - 21.*
>
> [emphasis added]

and,

> To ensure **dosing limited** to the respiratory tract and to be able to **precisely quantitate** the dose administered, leukotrienes are nebulized ... *Applicants' Specification, pg 53, ln 3 - 5.* [emphasis added]

Thus, contrary to the facts of *In re Rosicky,* Applicants's specification provides the requisite evidence of particular advantages of the both the i) form of the solution (i.e. aerosol) and ii)

the delivery vehicle. As such, the holding of *In re Rosicky* has no bearing on the present claims.

Third, the Examiner cites *In re Lerner, 169 USPQ 51 (1971).* Applicants submits that his case is similar to the *Rosicky* case and is likewise inapplicable to the present claims. Specifically, the *Lerner* decision notes that the limitation of a "carrier" in claim 4 of the particular application in question did not create a distinction over the art. However, a "carrier" is not analogous to limitations of the pending claims. A "carrier" is inert and frequently serves as nothing more than filler. By contrast, as noted above, the i) form of the solution (i.e. aerosol) and the ii) delivery vehicle both confer advantages.

Finally, the Examiner cites *In re Riden et al., 138 USPQ 112 (1963).* Applicants remind the Examiner that a court holding may not be asserted without a determination as to whether the holding is still valid. Applicants point out that the rationale and holding of *In re Riden et al.*, relative to an obviousness rejection based on a primary reference that does not disclose or suggest any usefulness of a claimed composition, has been overruled:

> The question remains whether ... Riden state[s] the correct burden of proof to be imposed on an applicant for patent ... We have concluded that [it] does not. ... To the extent that ... Riden [is] inconsistent with the views expressed herein, they no longer will be followed, and are overruled. *In re Stemniski, 58 CCPA 1410; 444 F2d 581, 170 USPQ 343 (1971).*

Applicants argue, as detailed above, that the instant specification provides an ample showing of the advantages and usefulness for a composition comprising an aerosol, and/or a solution in an endotracheal tube, bronchoscope or nebulizer. As held in *In re Stemniski*, it is not the Applicants' burden to prove a claim's non-obviousness to the Patent Office.

Thus, none of the four cases cited by the Examiner are applicable - let alone dispositive. None of the cases provides a basis or justification for ignoring the claim limitations at issue here.

B. When All Of The Claim Limitations Are Considered, The Obviousness Rejection Must Be Withdrawn

The Examiner's uses but a single reference as a basis for making an obviousness rejection. This reference - Gosselin *et al.* - provides no teaching or suggestion to use LTB_4 in conjunction with the particular delivery vehicles set forth in the pending claims. Since the above-noted case law provides no justification for ignoring Applicants' claim elements, merely relying on the Gosselin reference is insufficient to establish obviousness.

Moreover, Applicants have provided (see above) excerpts from the specification which detail the advantages of both the i) form of the solution, and ii) the delivery vehicle.[2] This *evidence* is offered to show that these claim limitations are unobvious and to rebut any assertion of obvious. In this regard, the Examiner is reminded that obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785 (Fed. Cir. 1984).

C. The Fact That Delivery Vehicles Are Known Is Irrelevant

The Examiner may be tempted to simply argue that there is no need to supplement the Gosselin reference - since delivery vehicles are known. Applicants wish to point out, however, that "[o]nly God works from nothing. Men must work with old elements." *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 225 USPQ 26, 31 n. 3 (Fed. Cir. 1985) (quoting from Markey, "Why Not the Statute," 65 JPOS 331, 333-334 (1983)).

The *Fromson* case is particularly relevant here. In that case, the inventor developed a process for photolithography using 1) aluminum as a substrate, 2) oxide coatings by anodization, 3) silication, and 4) application of light-sensitive resins. The district court correctly found that each of these elements individually were known in the art - but incorrectly concluded, on the basis of the unpatentability of each element, that the combination of these steps was unpatentable. On appeal, the Federal Circuit pointed to the "fundamental error" of the district court, noting: "At no point did the court indicate, nor does

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[2] The advantages include i) minimization of side effects; ii) minimization of systemic consequences; iii) limited dosing to the respiratory tract and iv) a precise quantitation of the administered dose. Gosselin *et al.* teaches none of these advantages.

the record indicate, a basis on which it can be said that the making of that combination would have been obvious when it was made." *Fromson, supra* at 31.

Similarly, in this case, the Examiner has not shown a basis for the particular combination of elements in the pending claim. Without such a showing, the Examiner's rejection must be withdrawn.

II. The Priority Statement Is Corrected

The Examiner requests correction of the priority statement in the written description as a result of the issuance of the parent application as United States Patent No. 5,909,734. The Applicants have provided herein the proper revisions to the initial priority statement found on page 3 of the New Application Transmittal Page filed March 3, 1999. Following this correction, the Applicants believe the specification is in final form for issuance and publication.

CONCLUSION

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.252.3353.

Dated: April 28, 2003

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APPENDIX I
MARKED-UP VERSION OF REWRITTEN CLAIMS
PURSUANT TO 37 CFR § 1.121 (c)(1)(ii)

22. (Twice Amended) A solution for the treatment of a microbial infection, said solution comprising a sterile liquid vehicle[~~, an antibiotic~~] and a leukotriene dissolved in said sterile liquid vehicle, wherein said solution is an aerosol[~~ized for administration to a subject~~].

28. (Twice Amended) A solution for the treatment of a microbial infection, said solution comprising a sterile liquid vehicle[~~, an antibiotic~~] and a leukotriene dissolved in said sterile liquid vehicle, wherein said solution is in [a] an intratracheal instillation device, said instillation device is selected from the group consisting of an endotracheal tube and a bronchoscope [~~for intratracheal administration to a subject~~].

33. (Amended) A composition for the treatment of a microbial infection comprising, a sterile liquid vehicle[~~, an antibiotic~~] and a leukotriene dissolved in said sterile liquid vehicle, wherein said solution is contained within a nebulizer.

Appendix III
MARKED-UP VERSION OF REWRITTEN PARAGRAPHS
PURSUANT TO 37 C.F.R. § 1.121(b)(1)(iii)

Page 1 Para 1.

Related Applications

This is a Divisional of copending application 08/757,136 filed on 12/03/96 issued as Patent No. 5,909,734 on 06/08/99.